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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,882	12/01/2000	William Lee	00786-429001 / MGH-1420.0	5708

7590

12/31/2001

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/31/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/728,882

Applicant(s)

Lee et al.

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-40 are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Claims 1-40 are pending and subject to restriction.

#### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, drawn to an *in vitro* method for removing virus from a sample with a membrane of pore size 20-1000 nm and engrafted with polymeric side chains, classified in class 422, subclass 261 and others.
- II. Claims 22-23, drawn to an *in vivo* method for removing virus from blood with a membrane of pore size 20-1000 nm and engrafted with tertiary amino groups, classified in class 604, subclass 4 and others.
- III. Claims 24-33, drawn to a device comprising a membrane of pore size 20-1000 nm, engrafted with functional groups that interact with viruses, classified in class 422, subclass 44 and others.
- IV. Claims 34-36, drawn to a method of generating virus particles comprising passing culture medium through a membrane of pore size 20-1000nm, engrafted with tertiary amino groups, classified in class 435, subclass 239 and others.
- V. Claims 37-40, drawn to a device comprising a bioreactor connected to a filter comprising a membrane with a pore size of 20-1000 nm, engrafted with tertiary amino groups, classified in class 435, subclass 289.1 and others.

The inventions are distinct, each from the other because of the following reasons:

The processes of Groups I, II and IV are distinct from one another because they recite different and distinct steps which lead to different and distinct products or end points. For example, the method of Group II is an *in vivo* method where blood is returned to a patient. The method of Groups I and IV do not require blood to be returned to a patient. The method of Group IV

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requires that the membrane be engrafted with tertiary amino groups while the method of Group I does not require this group.

The devices of Groups III and V are distinct because the bioreactor of Group V is not required in the device of Group III, thus, the devices are distinct.

Further, the method of Groups I, II and IV do not require the device of Group V. In particular, the method of Group IV does not require that the bioreactor and the filter unit be connected.

And the method of Groups I, II and IV do not require the device of Group III, because the method of Group I requires engrafted polymeric side chains, the methods of Group II and IV require engrafted tertiary amino groups, while the device of Group III requires engrafted functional groups which interact with viruses. Thus, the scope of each device is distinct.

The several inventions listed above are independent and distinct from one another as they have acquired a separate status in the art and require independent searches, particularly with regard to the literature searches. Clearly, a reference which would anticipate one of the above groups would not necessarily anticipate or even make obvious any of the others.

An undue burden would ensue from the examination of multiple methods which have distinct steps and end points. Burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

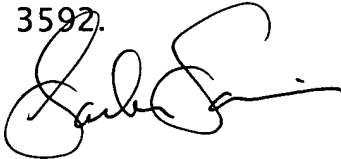
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an

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inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 6:00PM Tuesday-Friday and every other Monday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of papers is (703) 308-2742 or (703) 305-3592.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier  
Primary Examiner  
Art Unit 1651  
December 27, 2001